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NO. 7059 P. 1

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**PATENT, TRADEMARK, COPYRIGHT
AND UNFAIR COMPETITION LAW
AND RELATED LITIGATION**

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**TO: The Honorable Commissioner
Attention: Jean C. Witz
Art Unit 1651**

FROM: Beverly A. Lyman, Ph.D.

Fax No.: (703) 872-9306

Phone: (513) 241-2324

Date: September 4, 2003

Fax: (513) 421-7269

Pages (including cover page): 11

**Re: U.S. Serial No. 09/919,102 SELECTIVE ENZYME TREATMENT OF SKIN
CONDITIONS
Attorney Docket No. HOFE-02**

ATTACHMENTS/COMMENTS: OFFICIAL

Please deliver to Jean C. Witz

Duplicate Response to Restriction Requirement (2 pgs)

Return Postcard of Response to Restriction Requirement dated 11/4/02 (1 pg)

Copy of Response to Restriction Requirement dated 11/4/02 (4 pgs)

Copy of Reference of In re Weber, Soder, and Boksay (3 pgs)

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted
to the Patent and Trademark Office fax number (703) 872-9306 on the
date shown below.

Richard A. Stienne
Rhonda & Erianna

September 4, 2003
Date

Received from <513 241 6234> at 9/4/03 4:06:08 PM [Eastern Daylight Time]

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NO. 7059 P. 2

CERTIFICATE OF FACSIMILE

I hereby certify that this correspondence is being deposited via facsimile to The Honorable Commissioner in the United States Patent and Trademark Office, Attention: Jean C. Witz whose telephone number is (703) 308-3073 and fax number is (703) 872-9306 on September 4, 2003.

Rhonda A. Etienne 9/4/03
Rhonda A. Etienne Date

OFFICIAL PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Howard Fein, M.D.
Application No.: 09/919,102
Filed: July 31, 2001
Art Unit: 1651
Confirmation No.: 2446
Examiner: Jean C. Witz
Title: **SELECTIVE ENZYME TREATMENT OF SKIN CONDITIONS**
Atty. Docket No.: HOFE-02

Cincinnati, OH 45202

September 4, 2003

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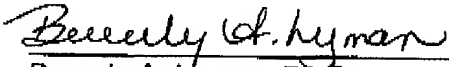
**DUPLICATE
RESPONSE TO RESTRICTION REQUIREMENT**

In response to Examiner's telephone call to applicant's undersigned representative today, applicant submits 1) a duplicate of the Response to the Examiner's Restriction mailed October 2, 2002
and 2) a copy of the postcard stamped by the Patent and Trademark Office indicating receipt of applicant's response mailed November 4, 2002 timely submitted.

Applicant believes no fees are due with this submission, but authorizes any fees to be charged fees to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS. L.L.P.


Beverly A. Lyman, Ph.D.
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NO. 7059 P. 4

Client/Matter: H0FE-02

WHE Docket No.: 46638

The stamp of the Patent Office hereon, may be taken as acknowledging the receipt, on the date stamped, of the following items in the captioned case:

Inventor(s): Howard Fein, M.D.

Serial No.: 09/919,102

Filing Date: July 31, 2001

Title:

SELECTIVE ENZYME TREATMENT OF SKIN

CONDITIONS

Enclosures: Response to Restriction Requirement; Preliminary
Amendment with Certificate of Mailing; and Return
Postcard

Beverly A. Lyman, Esquire

WOOD, HERRON & EVANS, L.L.P.

November 4, 2002



CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on November 4, 2002.

Kimberlee Fisher 11/4/02
Kimberlee Fisher Date

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Howard Fein, M.D.
Application No.: 09/919,102
Filed: July 31, 2001
Art Unit: 1651
Confirmation No.: 2446
Examiner: Jean C. Witz
Title: **SELECTIVE ENZYME TREATMENT OF SKIN CONDITIONS**
Atty. Docket No.: HOFE-02

Cincinnati, OH 45202

November 4, 2002

Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action mailed October 2, 2002 in the above-referenced application, applicant elects with traverse Group 1 (claims 1-10, 24-41), drawn to a method for treating a condition affecting at least one layer of the skin wherein the enzyme is trypsin.

However, applicant respectfully asserts that such a restriction is improper. Applicant has filed a Preliminary Amendment amending claims 1,2, 4-7, 9, 20, 21, 30, 34, 35, and 39-41 to recite a hydrolase. At the outset, applicant notes that amended claims 1-10 and 24-41 are now directed to methods for treating skin conditions with a composition that contains a hydrolase. Amended claims 11-20 (Group II) and amended claims 21-25 (Group III) are directed to a composition that contains various hydrolases, and claims to such compositions should not be restricted based on enzyme function. Applicant now provides the following analysis in support of his assertion regarding the impropriety of a species election.

First, the Examiner's restriction forces applicant to fragment the invention claimed within a single claim. Under *In re Weber, Soder, & Boksay*, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978) (copy attached) this is not permitted.

The invention in *Weber* related to cyclic diamine derivatives possessing a common psychotherapeutic property and was identified by a single generic formula expressed in Markush format. The instant invention relates to hydrolases, a class of transferases, possessing the common biochemical property of transferring a donor group to water. The hydrolases are expressed in Markush format; the selection of which hydrolase to use in the composition and method of treatment depends upon the layer or layers of skin to be treated.

In *Weber*, the court viewed the Examiner's restriction as tantamount to a refusal to examine. It held that the United States Patent and Trademark Office has the authority to restrict between claims of an application reciting one or more independent and

distinct inventions, but does not have the authority to require an applicant to divide up a single claim and present it in different applications; this would allow an Examiner, rather than an applicant, to define an invention in violation of 35 U.S.C. §121, ¶2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention", emphasis added). Weber at 332. While recognizing the need for efficiency in limiting each application to one invention, the court stated that

...in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights [of the applicant] are paramount.

Second, §803.02 of the MPEP states that if the claims have unity of invention, it is improper to refuse to examine "that which applicants regard as their invention". Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature as being essential to that utility.

With regard to the instant application, all of the method and composition claims as amended share a common class of enzyme, that is, the hydrolases, which have the same utility to transfer a donor group to water.

Applicant also respectfully disagrees with the Examiner's position that "in the instant case the method can be practiced with a materially different product such as an alpha-hydroxy acid." Alpha-hydroxy acids are conventionally used in over-the-counter cosmetics to cause nonspecific exfoliation or shedding of the skin surface. When these

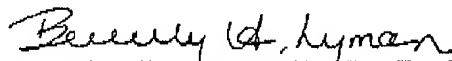
acids are used in higher concentrations than what is conventionally used in exfoliation cosmetics, they can cause nonspecific tissue damage such as the detachment of keratinocytes and epidermolysis. In applicant's instant applications, the hydrolases used in the composition and method produce selective tissue destruction limited to one or more layers of the skin that are involved with a certain skin condition.

For the reasons discussed, applicant respectfully requests that the Examiner reconsider the restriction requirement.

Applicant knows of no fee due with this submission, as November 2, 2002 was a Saturday. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.



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Court of Customs and Patent Appeals

In re Weber, Soder, and Boksay

No. 77-622 Decided June 30, 1978

PATENTS**1. Court of Customs and Patent Appeals — Jurisdiction (§28.25)**

Court of Customs and Patent Appeals has jurisdiction over "improper Markush claims" rejection and Section 121 rejections.

2. Claims — Broad or narrow — In general (§20.201)

Applicant is given, by statute, right to claim his invention, with limitations he regards as necessary to circumscribe invention, with proviso that application comply with requirements of Section 112.

3. Applications for patent — Divisional (§15.5)**Joinder of invention — In general (§42.01)**

Applicant has right to have each claim examined on merits, as general proposition; it may well be that pursuant to proper restriction requirement that number of claims submitted in one application will be dispersed to number of applications; such action would not affect right of applicant eventually to have each of claims examined in form he considers to best define his invention; however, single claim that is required to be divided up and presented in several applications would never be considered on its merits; totality of resulting fragmentary claims would not necessarily be equivalent of original claim; further, it is not inconceivable that number of fragments would not be described in specification, since subgenera would be defined by examiner rather than by applicant.

4. Applications for patent — Divisional (§15.5)**Commissioner of Patents — In general (§21.01)****Joinder of invention — In general (§42.01)****Pleading and practice in Patent Office — Rejections (§54.7)**

Section 121 provides Commissioner of Patents and Trademarks with authority to promulgate rules designed to restrict application to one of several claimed inven-

tions when those inventions are found to be "independent and distinct"; however, it does not provide basis for examiner acting under Commissioner's authority to reject particular claim on that same basis.

5. Applications for patent — Divisional (§15.5)**Claims — Broad or narrow — Markush type — In general (§20.2051)****Commissioner of Patents — In general (§21.01)****Joinder of invention — In general (§42.01)****Pleading and practice in Patent Office — Rejections (§54.7)**

Patent Office must have some means for controlling such administrative matters as examiner caseloads and amount of searching done per filing fee, even though statute allows applicant to claim his invention as he sees fit; Commissioner of Patents has authority to "establish charges for * * * services furnished by the Patent and Trademark Office." under 35 U.S.C. 41(b); statutory rights are paramount in drawing priorities between Commissioner as administrator and applicant as beneficiary of his statutory rights; rejection of claims under Section 121 violates basic right of applicant to claim his invention as he chooses.

6. Joinder of invention — In general (§42.01)**Pleading and practice in Patent Office — Rejections (§54.7)**

Restriction requirement and subsequent action of examiner in withdrawing nonelected claims from consideration does not, per se, constitute rejection; however, In re Haas, 179 USPQ 623, in which examiner's action in withdrawing claims was rejection, since "claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content," is exception.

Particular patents — Diamine Derivatives

Weber, Soder, and Boksay, Cyclic Diamine Derivatives, rejection of claims 1-6, 16, 17, 20, and 22 reversed and remanded; appeal of claims 8-13, and 23 dismissed.

Appeal from Patent and Trademark Office Board of Appeals.

At the outset, the board decided that §121 was an adequate legal basis for the examiner to reject a single claim "embracing" more than one independent and distinct invention. In support thereof, the board incorporated two board decisions⁵ which discussed the interrelated rejections of "misjoinder under 35 U.S.C. 121" and "as being improper Markush claims" as applied here. The board analyzed the claims in light of those decisions and found them to contain multiple independent and distinct inventions.

Appellants argue before this Court that each of the claims is directed to but a single invention and §121 is not a proper ground for rejection in any event.

Opinion

[1] The board affirmed the examiner's rejection of claims 1-6 "as being improper Markush claims and misjoinder under 35 U.S.C. 121." However, the reasoning of the board shows that the analysis of the "improper Markush claims" rejection was to be supportive of the rejection under §121 rather than alternative to it. We have jurisdiction over both rejections,⁶ but

⁵ The board incorporated both *Ex parte Dorlars*, Appeal No. 148-56, decided May 2, 1975, reproduced in the record, and *Ex parte Haas*, 188 USPQ 374 (Bd. App. 1975). The board stated in *Dorlars* that:

What we do find relevant is the single question: does the Examiner have legal authority to attack the propriety of an individual claim, whether of the Markush-type or otherwise, which includes a plurality of independent and distinct inventions? We think clearly the answer is "yes."

The board based its conclusion in *Dorlars* on §121 and further stated:

Clearly the mere fact that review of decisions requiring restriction within a single claim is available under 35 USC 134, whereas decisions requiring restriction between claims are not, cannot serve to limit application of the statute. That relates only to the issue of jurisdiction to review; it has no bearing on the scope of the statute itself — on the scope of authority conferred. In *Ex parte Haas*, the board decided that Rule 141, 37 CFR 1.141 regards an allowable generic claim as one that does not include more than one independent and distinct invention. The board decided that §121 is a legal basis for rejecting a single claim as an improper Markush claim.

⁶ 37 CFR 1.196(a) provides that in decisions of the board:

The affirmance of the rejection of a claim on any of the grounds specified constitutes a general affirmance of the decision of the pri-

mary examiner on that claim, except as to any ground specifically reversed.

[2] An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112. We have decided in the past that §112, second paragraph, which says in part "(t)he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it. *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

[3] As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.⁷

[4] It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inven-

tionary examiner on that claim, except as to any ground specifically reversed.

See also *In re Sichert*, 566 F.2d 1154, 1164, 196 USPQ 209, 217 (CCPA 1977).

⁷ See *Fields v. Conover*, 58 CCPA 1366, 443 F.2d 1386, 170 USPQ 276 (1971), wherein a subgenus was not described and *In re Ruschig*, 54 CCPA 1531, 379 F.2d 990, 154 USPQ 118 (1967), wherein a species of a properly described genus was found not to be described.

tions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

[5] Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee.⁸ But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount. We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

[6] Appellants contend that the examiner's action in withdrawing claims 8-13, 16, 17, 20, 22 and 23 from consideration as drawn to nonelected inventions constitutes a rejection under the holding of *In re Haas*, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973), and, therefore, the board improperly found a lack of jurisdiction. We do not agree. Clearly our decision in *In re Hengehold*, 58 CCPA 1099, 440 F.2d 1395, 169 USPQ 473 (1971), disposed of the theory that a restriction requirement and the subsequent action of the examiner in withdrawing nonelected claims from consideration,⁹ per se, constitutes a rejection.

An exception is found in *In re Haas*, supra, wherein we determined that the examiner's action in withdrawing claims was a rejection because the "claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content." 486 F.2d at 1056, 179 USPQ at 625. (Emphasis ours.) We do not understand the PTO to make such a holding with respect to claims 8-13, 16, 17, 20, 22 and 23, nor that appellants argue that the PTO does so. Indeed, we note that appellants admitted in their brief before the board that claims 8-13 and 23 were "properly withdrawable." Consequently, the board's dismissal of the appeal to claims 8-13 and 23 was correct. The Commissioner's brief admits that claims 16, 17, 20 and 22 contain species of the invention of generic claim 1 and would be provided an examination on the merits should the §121 rejection be reversed. We remand for appropriate action on claims 16, 17, 20 and 22, and dismiss the appeal of claims 8-13 and 23 for lack of jurisdiction.

The decision of the board affirming the rejection under §121 is reversed, and the case is remanded for consideration of the "improper Markush" rejection of claims 1-6 and appropriate action on claims 16, 17, 20 and 22. The appeal of claims 8-13 and 23 is dismissed for lack of jurisdiction.

Reversed and Remanded

Rich. Judge, concurring.

I concur in the result reached in the main opinion, but there are a few points I wish to make clear.

35 USC 121 deals with a matter of PTO practice known as "requirements for division" prior to the 1952 Patent Act which, for the first time, provided a statutory provision on this subject. It did so, under the heading "Divisional Applications," by giving the Commissioner a discretionary, unappealable power to restrict an application to one of several claimed inventions when those inventions were found to be "independent and distinct." 35 USC 121, first sentence; see also P. J. Federico, "Commentary on the New Patent Act" 35 USCA p. 1, at p. 34 (1954).

not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

⁸ We take notice of a practice formerly utilized by the PTO and found in the MPEP: 705 Patentability Reports

Where an application, properly assigned to one examining group, is found to contain one or more claims per se classifiable in one or more other groups, which claims are not divisible inter se or from the claims which govern classification of the application in the first group, the application may be referred to the other group or groups concerned for a report as to the patentability of certain designated claims. This report will be known as a Patentability Report (P.R.) and will be signed by the primary examiner in the reporting group.

The report, if legibly written, need not be typed.

Note that the Patentability Report practice is suspended, except in extraordinary circumstances. See §705.01(e).

We further note the authority of the Commissioner under 35 USC 41(b) to "establish charges for * * * services furnished by the Patent and Trademark Office."

⁹ 37 CFR 1.142(b) provides:

(b) Claims to the invention or inventions